IHCP bulletin

INDIANA HEALTH COVERAGE PROGRAMS

BT202010 FEBRUARY 11, 2020

IHCP expands coverage for genetic testing for breast cancer recurrence

Effective January 1, 2020, the Indiana Health Coverage Programs (IHCP) added the EndoPredict gene assay for breast cancer recurrence as a covered service. This service will be billed with procedure code 81522 – *Oncology (breast), mRNA gene expression analysis of 12 genes in breast tumor tissue*. Coverage applies to all IHCP programs, subject to limitations established with certain benefit packages. This policy applies to dates of service (DOS) on or after March 11, 2020, in accordance with the following policies and procedures.

Coverage parameters

The IHCP covers EndoPredict when it is considered medically necessary for managing the treatment of breast cancer. This gene assay looks specifically at patients who have been diagnosed with estrogen receptor positive and HER2 negative breast cancer. The test is used to determine the likelihood of distant recurrence and the probability of response to chemotherapy in patients. The test should be ordered in the context of a provider-patient discussion regarding



risk preferences when the test results aid in making decisions regarding chemotherapy.

Prior authorization requirements

All general prior authorization (PA) criteria must be met for any genetic testing service to be covered. For specific details on required PA documentation, general PA criteria, and PA criteria for cancer-susceptibility genetic testing, see the <u>Genetic Testing</u> provider reference module.

To obtain PA for the EndoPredict gene assay, all the following criteria must be met:

- Individual has had surgery and full pathological evaluation of the specimen has been completed.
- Histology is ductal, lobular, mixed, or metaplastic.
- Histology is not tubular or colloid.
- Estrogen receptor is positive (ER+), or progesterone receptor is positive (PR+), or both.
- HER2 receptor is negative.
- pN0 (node negative) or pN1mi with axillary lymph node micrometastasis is less than or equal to 2mm.
- Individual has one of the following:
 - Tumor size 0.6-1.0 cm moderate/poorly differentiated
 - Tumor size 0.6-1.0 cm well-differentiated with any of the following unfavorable features: angiolymphatic invasion, high nuclear grade, or high histologic grade
 - Tumor size greater than 1.0 cm and less than or equal to 4.0 cm
- Individual does not have a pT4 lesion.
- Chemotherapy is a therapeutic option being considered and will be supervised by the practitioner ordering the gene expression profile.

Gene expression profiling with the EndoPredict Breast Cancer Assay as a technique of managing the treatment of breast cancer is considered not medically necessary when the criteria listed have not been met. This test is limited to once in a lifetime per member.

Gene expression profiling as a technique of managing the treatment of breast cancer is considered investigational and not medically necessary when a gene profiling test other than the Oncotype DX or EndoPredict Breast Cancer Assay is being used, including but not limited to:

- Breast Cancer Gene Expression Ratio (also known as Theros H/ISM)
- Breast Cancer IndexSM
- Insight® DX Breast Cancer Profile
- MammaPrint® (also referred to as the "Amsterdam signature" or "70-gene signature")
- Mammostrat®
- Oncotype DX DCIS
- PAM50 Breast Cancer Intrinsic Classifier™
- The 41-gene signature assay
- The 76-gene "Rotterdam signature" assay
- THEROS Breast Cancer IndexSM

Gene expression profiling as a technique of managing the treatment of ductal carcinoma in situ (DCIS) is considered investigational and not medically necessary under all circumstances.

Reimbursement

The following reimbursement information applies:

- Pricing: Maximum fee
- Prior authorization: Required
- Billing guidance: Standard billing guidance applies

The Professional Fee Schedule, accessible from the IHCP Fee Schedules page at in.gov/medicaid/providers, will be updated to reflect coverage and reimbursement information. Reimbursement, PA, and billing information applies to services delivered under the fee-for-service (FFS) delivery system. Individual managed care entities (MCEs) establish and publish reimbursement, PA, and billing criteria within the managed care delivery system. Questions about managed care billing and PA should be directed to the MCE with which the member is enrolled.



QUESTIONS?

If you have questions about this publication, please contact Customer Assistance at 1-800-457-4584.

COPIES OF THIS PUBLICATION

If you need additional copies of this publication, please download them from the <u>Bulletins</u> page of the IHCP provider website at in.gov/medicaid/providers.

TO PRINT

A <u>printer-friendly version</u> of this publication, in black and white and without photos, is available for your convenience.

SIGN UP FOR IHCP EMAIL NOTIFICATIONS

To receive email notices of IHCP publications, subscribe by clicking the blue subscription envelope or sign up from the HCP provider website at in.gov/medicaid/providers.

IHCP LISTENS

Do you have feedback for the IHCP? Help us serve you better by giving thoughts and suggestions about our provider engagement at IHCPListens@fssa.in.gov. This inbox helps solicit input from the provider community about workshops, webinars, and other presentations made on behalf of the IHCP. Providers may also email this inbox with ideas for future workshops and presentations, and questions about policies and programs.